UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

v. **No. 4:21-cv-01058-P**

FOOD AND DRUG ADMINISTRATION,

Defendant.

OPINION AND ORDER

Before the Court is the Motion to Alter Judgment filed by Defendant Food and Drug Administration (the "FDA"). ECF No. 103. In its Motion, the FDA asks the Court to impede and suspend the release of documents related to the emergency-approval of the Pfizer COVID-19 vaccine for an indefinite and unspecified amount of time. These documents should have been produced months ago under the Court's previous orders and the undersigned is exhausted by the FDA's continued attempts to pause the production of information related to one of the preeminent events of our time—the COVID-19 pandemic.

The Court has previously emphasized that the basic purpose of the Freedom of Information Act ("FOIA") is to ensure an informed citizenry and to pierce the veil of administrative secrecy. A fellow Texan, President Lyndon B. Johnson, upon signing FOIA into law, stated: "A democracy works best when the people have all the information that the security of the Nation permits. No one should be able to pull curtains of secrecy around decisions which can be revealed without injury to the public interest." President Lyndon B. Johnson, *Statement by the President Upon Signing the "Freedom of Information Act,"* July 4, 1966, https://www.presidency.ucsb.edu/documents/statement-the-president-upon-signing-the-freedom-information-act.

Information is the currency of democracy—and information is useful only if it is timely. Thus, unless instructed to do so from a higher court, this Court cannot allow the FDA to continue its devaluation of this essential information through its delay and obfuscation. *Env't Texas Citizen Lobby, Inc. v. ExxonMobil Corp.*, 123 F.4th 309, 311 (5th Cir. 2024) ("Justice delayed is justice denied."). Consequently, having considered the briefing and applicable legal authorities, the Court will **DENY** the FDA's request for an indefinite stay of production for the reasons stated herein.

BACKGROUND

This case was filed on September 16, 2021, and it is the oldest active case on the undersigned's docket. On January 6, 2022, the Court entered an order setting a production schedule, which was partially modified on February 2, 2022. The production schedule required the FDA to "produce 80,000 pages on or before May 2, June 1, and July 1, 2022; 70,000 pages on or before August 1, 2022; and then 55,000 pages on or before the first business day of each month thereafter." Additionally, the Parties were ordered to file a Joint Status Report every ninety days, apprising the Court of the production's progress.

On December 19, 2023, in a Joint Status Report, the FDA notified the Court that it had completed its production of responsive documents. However, on April 23, 2024, in a related case also before the undersigned, Plaintiff learned that the FDA may have identified but not produced an Emergency Use Authorization ("EUA") file. Thereafter, on July 17, 2024, in its response to Plaintiff's adequacy-of-search letter, the FDA disclosed that it had in fact identified but not produced an EUA file for the Pfizer Vaccine. *Id.* Because the Parties were unable to resolve this issue without court intervention, the matter was briefed. And on December 6, 2024, the Court entered an order finding that the EUA file was responsive to Plaintiff's FOIA request and must be produced. The Court ordered the FDA to produce the EUA file on or before June 30, 2025. The FDA now requests that the Court not only delay the production of the EUA file, but indefinitely stay it.

LEGAL STANDARD

A motion to alter judgment under Federal Rule of Civil Procedure ("Rule") 59(e) is appropriate: (1) where there has been an intervening change in the controlling law; (2) where the movant presents newly discovered evidence that was previously unavailable; or (3) to correct a manifest error of law or fact. *Schiller v. Physicians Res. Grp. Inc.*, 342 F.3d 563, 567 (5th Cir. 2003) (internal citations omitted). But a motion under Rule 59 cannot be used to raise arguments or claims "that could, and should, have been made before the judgment issued." *Marseilles Homeowners Condo. Ass'n v. Fidelity Nat. Ins. Co.*, 542 F.3d 1053, 1058 (5th Cir. 2008) (per curiam) (internal citation omitted). District courts enjoy discretion in deciding whether to reopen a case under Rule 59(e). *Weber v. Roadway Exp., Inc.*, 199 F.3d 270, 276 (5th Cir. 2000) (citing *Edward H. Bohlin Co. v. Banning Co.*, 6 F.3d 350, 353 (5th Cir. 1993)). "Reconsideration of a judgment after its entry is an extraordinary remedy that should be used sparingly." *Templet v. Hydrochem Inc.*, 367 F.3d 473, 479 (5th Cir. 2004). In striving to strike a balance between the need for finality and the need to render just decisions on the basis of all the facts, "the Fifth Circuit has observed that Rule 59(e) favor[s] the denial of [these motions.]" *Greenidge v. Carter*, No. 3:21-cv-1868-L, 2024 WL 4183523, at *1 (N.D. Tex. May 21, 2024) (Lindsay, J.) (cleaned up) (citing *S. Constructors Grp., Inc. v. Dynalectric Co.*, 2 F.3d 606, 611 (5th Cir. 1993)).

ANALYSIS

The FDA argues that the Court should alter or amend its order for the FDA to produce the EUA file on or before June 30, 2025, because: (1) the Court committed a manifest error by "never consider[ing] the timing necessary to search for and process further records, the availability of agency resources, or the agency's other processing obligations and responsibilities under FOIA;" (2) "exceptional circumstances exist given this Court's production order in *PHMPT II*[1] and the agency's other essential FOIA obligations;" and (3) the FDA is "exercising due diligence

[1]*PHMPT II* refers to a sister-case that is also on the undersigned's docket. *See PHMPT v. FDA*, No. 4:22-cv-915-P.

and has made, and continues to make, extraordinary efforts to hire, train, and otherwise maximize efficiencies to comply with this Court's Orders." ECF No. 104 (cleaned up).

As a preliminary matter, in its Cross-Motion for Summary Judgment, Plaintiff specifically requested that the Court order the FDA to produce the EUA file **on or before February 20, 2025**. ECF No. 94 at 22 (emphasis added). The FDA had the opportunity, in its Response, to explain why it should not be ordered to produce the documents so expeditiously, but it wholly failed to do so. *See generally* ECF Nos. 97, 98. Consequently, because the FDA's Motion does not present an intervening change in the controlling law or newly discovered evidence that was previously unavailable, the Court would be justified in denying this Motion because it presents numerous arguments and claims "that could, and should, have been made before the judgment issued." *Fidelity Nat. Ins. Co.*, 542 F.3d at 1058. Nevertheless, the Court finds it prudent to address each argument in turn.

A. Clear Error and/or Manifest Injustice

First, the FDA argues that the Court committed clear error "in imposing the . . . deadline . . . [without] considering the timing necessary to search for and process further records, the availability of agency resources, []or the agency's other processing obligations and responsibilities under FOIA" because "[n]either party briefed the feasibility of meeting a June 30, 2025 production deadline."[2] ECF No. 104 at 22–23 (cleaned up). The FDA's argument falls flat.

[2]In support of its assertion that the Court did not consider the agency's other processing obligations, the FDA claims that there are 135 requests that "were received [] before Plaintiff's FOIA request in this case." ECF No. 104 at 23. However, having reviewed the examples presented in the brief, as well as the appendix, the Court notes that these requests were filed in 2023 and 2024—years after the request in this case. If the FDA's contention is that the Court's order for it to produce the responsive EUA file is a new request, that gets placed at the bottom of the list, it is plainly mistaken. The request for the EUA file—along with the other responsive documents—was made back in 2021. Therefore, the Court's order evidences the FDA's continued obligation to produce responsive documents for a 2021 request, which far predates the examples provided by the FDA.

"[C]lairvoyance is not a power vested in the judiciary under Article III of the Constitution. . . ." *Gipson v. Weatherford Coll.*, No. 4:22-CV-0730-P, 2023 WL 8539847, at *1 (N.D. Tex. Dec. 11, 2023) (Pittman, J.). As discussed above, Plaintiff raised the issue of a production schedule, and the FDA chose not to respond. Despite the FDA's failure to respond, the Court—after considering the history of this case[3] and the challenges that may be presented in accomplishing the production—*sua sponte* gave the FDA an extension of over four months. Specifically, the Court considered that: (1) the Court's original order setting a production schedule was entered *over three years ago*; (2) the FDA knew about the EUA file well before its existence was disclosed to Plaintiff or the Court; (3) the EUA file was undoubtedly responsive to Plaintiff's FOIA request and should have been produced along with the other responsive documents; (4) the EUA file purportedly contained just over one-million pages; (5) the FDA last produced a document in this case on November 1, 2023—over fourteen months ago; and (6) the FDA would have produced the EUA file in roughly eighteen months had it continued production according to the Court's schedule.[4]

After considering the aforementioned, the Court determined that it was appropriate to set the production deadline for a few months after the date that the production would have been completed if the FDA had not ceased its production in this case. To be clear, the Court's order granting summary judgment was not in response to a new FOIA request and did not create a new production burden. Rather, it simply required the FDA to finish its production of responsive documents based on the original schedule and FOIA request. The FDA has had ample

[3]In this case, the Court has repeatedly recognized the "unduly burdensome" challenges that this FOIA request has presented to the FDA. *See generally* ECF Nos. 23, 30, 34. But, as the Court has also previously expressed, there may not be a "more important issue at the Food and Drug Administration . . . than the pandemic, the Pfizer vaccine, getting every American vaccinated, [and] making sure that the American public is assured that this was not [rushed] on behalf of the United States. . . ." ECF No. 34 at 46. In other words, the Court has placed a burden on the FDA that it feels is appropriate in light of the unique significance of the request.

[4]1,000,000 pages/55,000 pages per month=18.2 months.

opportunity and time to process and produce the EUA file. If the FDA was truly worried about efficiency—at any point during its twenty-two-month production effort, and not twelve months after its completion—it should have disclosed the existence of the EUA file to Plaintiff and asked the Court to determine its responsiveness. Instead, the FDA attempted to hide the file's existence until roughly eight months **after** it had "completed production." Consequently, the undersigned finds that the FDA has failed to show that the Court committed a manifest error in law or fact by setting the June 30, 2025 deadline.[5]

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[5]The FDA's brief is riddled with quotations from cases before the United States District Court for the District of Columbia. These quotes make clear that the FDA has consistently grumbled about this Court and its orders in this case and *PHMPT II*. The Court, however, was most disturbed by Judge Randolph D. Moss's statement alleging that this Court is somehow "jumping the queue." *See* ECF No. 104 at 23. The undersigned was not disturbed because it evidences the FDA's criticism, but because it demonstrates that the FDA has presented this Court's production orders as inconsiderate and disrespectful to other judges and their dockets. If true, this is false and inflammatory. *See Dondi Properties Corp. v. Com. Sav. & Loan Ass'n*, 121 F.R.D. 284, 295 (N.D. Tex. 1988) ("To the office of judge, a lawyer owes respect, diligence, candor and punctuality, the maintenance of the dignity and independence of the judiciary, and protection against unjust and improper criticism and attack. . . .").

Seemingly, the FDA is presenting the circumstances of this case in such a manner that it appears this Court is jumping the queue with its orders. The undersigned is sympathetic to Judge Moss's frustration regarding another court usurping his inherent authority to control his docket. *See, e.g., Chamber of Com. of U.S. v. Consumer Fin. Prot. Bureau*, 733 F. Supp. 3d 558 (N.D. Tex. 2024). But that is not the case here. The Court assures Judge Moss, and all other concerned judges, that the Court means no disrespect, nor does it wish to manifestly affect any judge's ability to control their docket. The undersigned simply wishes to bring about the resolution of this ancient case, which came first in temporal proximity with regard to the FOIA request, filing of the case, and the Court's order.

As discussed above, the June 30, 2025 production deadline is not based upon a new production obligation or new FOIA request. Rather, it is a deadline imposed on a production of documents that stalled for fourteen months and, as a consequence, is well past its sell-by date. The undersigned agrees that "comity runs both ways," and if the undersigned is ever presented with the opportunity to show deference to Judge Moss, or any other judge, and wait in "the queue," he will happily do so. However, because this case is almost four years old and the production should have already occurred, the FDA's new arguments do not change the Court's analysis here. The FDA cannot refuse to

B. Exceptional Circumstances

Second, the FDA essentially argues that exceptional circumstances exist because—in an age where the length of rules and regulations number not in the hundreds but the hundreds of thousands[6]—the agency tasked with processing and producing responsive documents for the Nation's FOIA requests is staffed by ten people. *See* ECF No. 104 at 13 ("ALFOI[7] was able to keep its FOIA queues relatively low and stable with nine regular staff and one branch chief."). While the agency has hired fourteen new employees since this case began, the FDA contends that it takes **two years**[8] for each of those employees to be fully trained and capable of doing their jobs. *See id.* at 14–15. In support of its argument, the FDA cites to multiple cases out of the United States District Court for the District of Columbia. *See id.* at 14–16. The FDA offers these cases to show that the Court's production orders are exceptional and onerous because they far exceed the "normal" production rate of only 500-pages per month. *Id.*

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produce responsive documents and then further delay because new cases have since arisen.

[6]*See, e.g.*, Clyde Wayne Crews Jr., *2024 Federal Register Page Count is Highest Ever*, FORBES, https://www.forbes.com/sites/waynecrews/2024/12/31/bidens-2024-federal-register-page-count-is-highest-ever/ (the 2024 register contains 107,262 pages and 3,248 final rules and regulations).

[7]Access Litigation and Freedom of Information, a branch of the FDA's Center for Biologics Evaluation and Research.

[8]To say that the Court was astounded by the length of time new-ALFOI employees must be trained before they are allowed to do their jobs is an understatement. After being appointed, the undersigned was given one week of training at what is affectionately referred to as "baby judge school." In fact, the entire COVID-19 pandemic itself lasted around two years. *See* President Joe Biden, 60 Minutes (@60Minutes), X (Sept. 18, 2022, 7:09 PM), https://tinyurl.com/2s35maau (declaring the COVID-19 pandemic over). You can also walk across the continental United States in less than two years. *See* https://texags.com/s/17847/john-ball-the-walking-aggie-completes-his-cross-country-trek. And, most notably, becoming a Navy Seal, a Green Beret, or an Astronaut takes less than two years. *See* https://special-ops.org/time-to-fully-qualified-navy-seal-or-green-beret/; https://www.nasa.gov/humans-in space/astronauts/astronaut-selection-program/.

The Court has previously noted the importance of the public's ability to have access to the information derived from Plaintiff's FOIA request in an expedited manner and not in the 75 years the FDA originally requested—when most of those who took the Pfizer vaccine are long passed. *See* ECF No. 35. Americans are capable of doing great things in times of crisis, from thirteen colonies uniting to defeat the British Empire, to executing the Berlin Airlift, to putting a man on the moon, the citizens and government of the United States have consistently shown the ability to overcome difficult and seemingly impossible circumstances. In fact, despite representing that doing so would be unduly burdensome or impossible, the FDA has shown some of that same resiliency and thus far has risen to the challenge of complying with the Court's orders. The Court is confident that it will do so again here.[9] Therefore, the Court finds that the FDA has failed to show exceptional circumstances that warrant indefinitely staying the production schedule.

C. Due Diligence

Third, and finally, the FDA argues that it has demonstrated due diligence through its efforts to comply with the Court's prior orders while handling other FOIA requests. ECF No. 104 at 16–19. Here, the FDA reasserts and rehashes most of its exceptional-circumstances argument. The Court agrees that the FDA has demonstrated due diligence in complying with the Court's prior orders. And, as discussed above, the Court is confident that it can continue to do so. Consequently, the Court finds that the FDA's due diligence does not warrant an indefinite stay of production in this case.

[9]The FDA reviewed and approved the Pfizer vaccine for emergency use in an unprecedented amount of time. Every American was urged or forced to take a COVID-19 vaccine. Surely, documents supporting the approval can be released to the public in seven months. Unprecedented times call for unprecedented actions. As Abraham Lincoln stated: "I am a firm believer in the people and, if given the truth, they can be depended on to meet any national crisis. The point is to bring before them the real facts." Carl Jenson, STORIES THAT CHANGED AMERICA: MUCKRAKERS OF THE 20TH CENTURY, at 23, (2002).

CONCLUSION

From the beginning of this case, the undersigned—without much, if any, precedent from the Fifth Circuit—has been tasked with determining what the appropriate rate of production is for arguably the most important FOIA request in American history. Plaintiff filed this case seeking an expedited production schedule for documents and information related to a vaccine that was developed in response to a once-in-a-hundred-year pandemic. *See Sambrano, et al. v. United Airlines, Inc.*, 707 F. Supp. 3d 652, 664 (N.D. Tex. 2023) (Pittman, J.) ("The COVID-19 pandemic was a once in a century event, unprecedented in the modern era . . . ."). Hundreds of millions of Americans were urged—and some coerced—into taking a vaccine that was developed, and approved for emergency use, at an unprecedented rate. The FDA wanted 75 years to produce the responsive documents.[10] It is axiomatic that information which directly effects every American could not be produced at such a snail's pace. Thus, the Court, noting that "stale information is of little value," ordered production at what has been described as an extraordinary rate. *See* ECF No. 35 (internal citation omitted); *see generally* ECF No. 104.

While it is evident that the FDA has spilled much ink in the United States District Court for the District of Columbia about the unfairness of the Court's production orders in this case and *PHMPT II*, the FDA has not challenged any of the Court's orders on appeal and has largely complied with them. The undersigned has suffered from a lack of guidance from the Fifth Circuit on what is appropriate and what is "unfair" in this case. The Court has made its decision, but it encourages the FDA to seek whatever appellate remedy is appropriate—up to and including mandamus—from the Fifth Circuit. But, as far as this Court is concerned, to quote the undersigned's predecessor, the late Judge Eldon B. Mahon: "Let the chips fall where they may." *Sony Music Ent.*

[10]The Court notes that the FDA's seventy-five-year request did not include the production of the EUA file which essentially doubled the number of responsive pages. So, presumably, the FDA would have needed an additional seventy-five years to produce the EUA file. In that case, the FDA would finish its production in the year 2171.

Inc. v. Clark-Rainbolt, No. 4:23-CV-0275-P, 2023 WL 3993191, at *2 (N.D. Tex. June 14, 2023) (Pittman, J.); *see also Galyean v. Guinn*, No. 4:21-CV-1287-BJ, 2023 WL 8006412, at *12 (N.D. Tex. Nov. 17, 2023) (Cureton, M.J.).

"Truth will ultimately prevail where pains [are] taken to bring it to light."[11] Because the arguments presented in the FDA's Motion are arguments and claims that could, and should, have been made before the judgment was issued, and for the other reasons set out above, the FDA's Motion to Alter Judgment (ECF No. 103) is **DENIED**. The FDA shall produce the responsive EUA file **on or before June 30, 2025.**

SO ORDERED on this **10th day of January 2025.**

Mark T. Pittman

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE

[11] *George Washington,* LETTER TO CHARLES M. THURSTON (August 10, 1794), available at https://founders.archives.gov/documents/Washington/05-16-02-0376.